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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,823	10/23/2003	David Grewe	CRD1061CIP1	6328

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,823	Applicant(s) GREWE ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 03/27/2006, amended claims 1, 4, 18, 19, 22, 23, and 26 are acknowledged. The current objections and rejections of the claims 1-39 are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 03/28/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Objections

3. Claim 18 is objected to because of the following informalities:
4. The term "about" in claim 18 is a relative term that appears to render the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The thicknesses of the deflection and retaining ribbons are unclear.
5. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7 and 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al (US 5,060,660) in view of Mirigian (US 2003/0105415). Gambale et al discloses the claimed invention, including the following:

9. Regarding claims 1, 19, and 23, Gambale et al discloses a steerable guidewire comprising an elongate flexible shaft 32, a flexible helical spring 42 providing torsional rigidity and having multiple turns, a rectangular cross section, and attached to the distal region of the tubing member (column 5 line 65 – column 6 line 30), a elongated deflection member 46 having a cylindrical cross section and slidably disposed within said tubing and said coil having a flattened distal profile (column 6 lines 35-52), a retaining ribbon 62 attached to the distal end of the tubing member and oriented generally parallel to the flattened deflection member, and a rounded attachment member 44 engaging the distal ends of the coil, deflection member, and retaining ribbon such that a push/pull of said deflection member causes bi-directional deflection.

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10. Regarding claims 4, 22, and 26, Gambale et al discloses an elongated deflection member 46 with a square cross section (column 6 lines 35-52).

11. Regarding claims 5 and 27, Gambale et al discloses said retaining and deflection ribbons in a normally biased and arcuate configuration causing the distal end of said coil to be curved in a resting position (column 3 line 67 – column 4 line 2).

12. Regarding claims 6 and 28, Gambale et al discloses a deflection member with a circular cross section in the proximal region that extends to the distal portion of the tubing (column 7 lines 38-32).

13. Regarding claim 7, Gambale et al discloses said retaining ribbon 62 extending from the distal region of the flexible tubing to approximately distal end of the flexible helical coil.

14. Gambale et al discloses the claimed invention except for (a) the flexible helical coil having interlocking undulations disposed lateral to the length of the flexible tubing and (b) disposing the windings of the helical coil in such a manner as to create a square or sin wave profile. Mirigian teaches a guidewire 10 having a flexible helical coil 22 having interlocking undulations 32 disposed lateral to the length of the flexible tubing and (b) disposing the windings of the helical coil in such a manner as to create a square or sin wave profile, as best seen in Figures 1, and 3-11 (paragraphs 16-17, 26-29, and 46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Gambale et al, with the interlocking windings of the helical coil as taught by Mirigian for the purpose of

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configuring the mechanical properties of a guidewire, such as torque transmission, in a manner beneficial to navigating tortuous vasculature.

15. Claims 8, 10-13, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al in view of Schaer et al (US 5,882,333). For claim 8, Gambale et al discloses the claimed steerable guidewire except for the attachment member being a rounded bead. Schaer et al teaches an attachment member 35 in the form of a rounded bead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Gambale et al, with Schaer et al for the purpose of embedding the coil, deflection ribbon, and retaining ribbon in a manner beneficial to navigating tortuous vasculature.

16. For claims 10-13 and 29-32, Gambale et al discloses the claimed steerable guidewire, including the attachment member contacting the helical coil to form a circular surface within which the deflection and retaining ribbons engage said surface at a location offset (and opposite each other) of the center and joining the ribbons as best seen in Figure 4b, except for the attachment member being a rounded bead. Schaer et al teaches an attachment member 35 in the form of a rounded bead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Gambale et al, with Schaer et al for the purpose of embedding the coil, deflection ribbon, and retaining ribbon in a manner beneficial to navigating tortuous vasculature.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al in view of Schaer et al and in further view of Hayzelden et al (US 2002/0165534).

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For claim 9, Gambale et al and Schaer et al disclose the claimed steerable guidewire except for forming the rounded bead with epoxy. Hayzelden et al teaches an attachment member 50 composed of epoxy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Gambale et al and Schaer et al, with Hayzelden et al for the purpose of embedding the coil, deflection ribbon, and retaining ribbon in an material with appropriate biocompatibility.

18. Claims 14-15 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al in view of Schaer et al and in further view of Hayzelden et al.

Gambale et al and Schaer et al disclose the claimed steerable guidewire except for the deflection and retaining ribbons forming a single unitary element having a generally U-shaped configuration providing a predetermined spacing between the ribbons oriented parallel to each other. Hayzelden et al teaches a unitary U-shaped deflection/retaining member 48 with a predetermined spacing between the two opposing regions oriented parallel to each other. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Gambale et al and Schaer et al, with Hayzelden et al for the purpose of embedding the maintaining the configuration of the deflection/retaining ribbon in a manner beneficial to navigating tortuous vasculature and retaining a desirable shape configuration prior to insertion.

19. Claims 16-18 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al in view of Schaer et al and Hayzelden et al and in further view of Palermo (US 4,886,067). Gambale et al, Schaer et al, and Hayzelden et

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al disclose the claimed steerable guidewire, including the thickness of the flattened deflection/retaining member's distal portion being 0.001 – 0.003 inches (Gambale et al, column 6 lines 64-69), except for intermittent flattened versus rounded portions of the deflection/retaining ribbon(s) and the distal tapering of the thickness. Palermo teaches a guidewire with a circular cross section wire/ribbon progressively flattened in the distal direction (column 1 lines 62-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Gambale et al, Schaer et al, and Hayzelden et al, with Palermo for the purpose of configuring the distal region of the deflection/retaining ribbon in a manner beneficial to attaining torsional rigidity and increased flexibility whilst navigating tortuous vasculature while simultaneously retaining a desirable shape prior to insertion.

20. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al in view of Palermo. Gambale et al discloses the claimed steerable guidewire system except for the flexible tubing and deflection member coupled to a control handle comprising a release mechanism is provided for guidewire detachment, a movable knob for longitudinal deflection of the deflection member in the distal direction, and wherein the deflection member extends the entire length of the handle. Palermo teaches a control handle 53 coupled to flexible tubing 20 and deflection member 44 with a movable knob 66 to impart distal curvature wherein the deflection member extends the entire length of the handle and beyond as best seen in Figure 4 and wherein when the retention member 70 is removed the guidewire is removably detached from said handle. It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify the guidewire system as taught by Gambale et al, with Palermo et al for the purpose of configuring the steerable guidewire system with mechanisms to attach/remove the guidewire with/from a handle including a knob to control the distal curvature of the guidewire for navigating tortuous vasculature.

Response to Arguments

21. Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Peters et al (US 2002/0038129) and Bagaoisan et al (US 6,355,016). Peter et al and Bagaoisan et al disclose intravascular navigation devices with similar structure to the as claimed instant case.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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